

INSTRUCTIONS FOR USE

IMPORTANT INFORMATION – PLEASE READ BEFORE USE

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS

The StabiliT Vertebral Augmentation System is intended for percutaneous delivery of StabiliT ER² Bone Cement in kyphoplasty procedures in the treatment of pathological fractures of the vertebrae. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

DESCRIPTION

The StabiliT Vertebral Augmentation System is a system for the controlled delivery of StabiliT ER² Bone Cement in the treatment of vertebral compression fractures. It contains an integrated low power bipolar radiofrequency (RF) warming source that warms the bone cement.

The StabiliT Vertebral Augmentation System consists of eight (8) components (Figure 1).

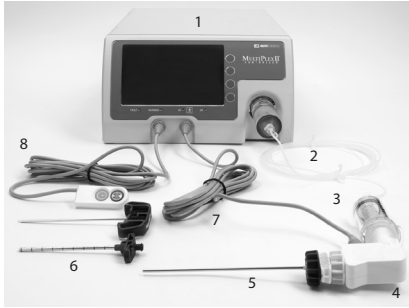


FIGURE 1. STABILIT VERTEBRAL AUGMENTATION SYSTEM

- One MultiPlex Controller or MultiPlex II Controller (#1, Controller) (including a power cord) and seven packaged sterile, disposable assemblies:
- Hydraulic Sub Assembly (HSA) (#2)
- Master Syringe (MS) (#3)
- Activation Element (AE) (#4)
- Locking Delivery Cannula (LDC) (#5)
- StabiliT Introducer - Working Cannula and Stylet (#6)
- AE Cable (#7)
- Hand Switch Cable (#8): The Hand Switch has two button functions:
 - BLUE Button – RF Activated Bone Cement at 1.3 cc/min
 - To activate BLUE Button on Hand Switch, PRESS ONCE to engage. PRESS AGAIN to disengage.
 - ORANGE Button – Second Timer
 - To activate ORANGE Button on Hand Switch function, press once to start second timer. To extinguish second timer press and hold for three seconds.

HOW SUPPLIED

- The Controller (including Power Cord) are provided non-sterile.
- The LDC, StabiliT Introducer, AE, Hydraulic Sub Assembly, Master Syringe, AE Cable, and Hand Switch Cable are provided sterile. These devices are intended for single use only. DO NOT re-sterilize and/or reuse. DO NOT use if package is open or damaged and notify the manufacturer.

CONTRAINDICATIONS

- The use of this product is contraindicated in patients with coagulation disorders, or with severe pulmonary insufficiency.
- The use of this product is contraindicated in patients with a compromise in the posterior column of the vertebral body or the walls of the pedicles.
- The use of PMMA bone cement is contraindicated in the presence of active or incompletely treated infection at the site where the bone cement is to be applied.
- This product should not be used in patients with sensitivity to any of the components of the PMMA bone cement.

WARNINGS

- Cement leakage may cause tissue damage, nerve or circulatory problems and other serious adverse events.
- This device should only be used by qualified physicians with training in the clinical procedure in which it is being used.
- For safe and effective use of the StabiliT Vertebral Augmentation System, the physician should have specific training, experience, and thorough familiarity with the use and application of this product.
- Percutaneous kyphoplasty procedures should only be performed in medical settings in which emergency decompressive surgery is available.
- It is essential to maintain strict sterile technique during the kyphoplasty procedure and during all phases of handling this product.
- Precise Locking Delivery Cannula placement is required for this procedure. Incorrect device placement could result in patient injury.

- The Working Cannula (part of StabiliT Introducer) is not intended for delivering bone cement. Always use the LDC to deliver bone cement to the vertebral body.
- Insertion of the Working Cannula must be performed with the Stylet in place inside the Working Cannula.
- The Introducer Stylet or the Osteotome or the LDC must be within the Working Cannula during, manipulation or repositioning of the Working Cannula.
- Removal of the Working Cannula must be performed by rotation and axial motion. DO NOT bend the Working Cannula sideways, patient injury may occur.
- Use appropriate imaging techniques to confirm correct LDC placement, absence of damage to surrounding structures, and appropriate location of delivered bone cement. Imaging, such as venography, can be used to assess the ability of the vertebra to contain the delivered bone cement.
- Thoroughly read the IFU that is packaged with the StabiliT ER² Bone Cement and the ER² Saturate Mixing System before use.
- Dispose used product per Local, State and Federal Bloodborne pathogen controls including Biohazard sharps container and disposal procedures.
- The StabiliT Vertebral Augmentation System can be used in conjunction with the Vertecor StraightLine Cement Staging Osteotome (per IFU) or Vertecor MidLine Cement Staging Osteotome (per IFU). Thoroughly read IFUs prior to use.
- Hydraulic Sub Assembly & Master Syringe failure may result in inability to deliver StabiliT ER² Bone Cement:
 - If the Hydraulic Sub Assembly & Master Syringe fails PRIOR to attachment to the AE press the REMIX/RESTART Button on the Controller and replace with a new Hydraulic Sub Assembly & Master Syringe.
 - If the Hydraulic Sub Assembly & Master Syringe fails AFTER bone cement has been delivered through the AE press REMIX/RESTART Button on the Controller and replace Hydraulic Sub Assembly & Master Syringe and AE.
- All devices except for the Controller are provided sterile. These devices are intended for single use only. DO NOT re-sterilize. DO NOT use if package is open or damaged. Reconditioning, refurbishing, repair, modification, or resterilization of the device(s) to enable further use is expressly prohibited as it may result in loss of function and/or infection.
- For devices penetrating bone, DO NOT use if dense bone is encountered. Device damage resulting in patient injury may occur. Breakage of the device may require intervention for retrieval.
- Instructions For Use (IFU) for each device (if packaged separately or along with this IFU) must be followed to perform a procedure using the StabiliT Vertebral Augmentation System.

CAUTIONS

- Examine all packaging prior to opening. DO NOT use device if damaged or the sterile packaging is breached.
- StabiliT Vertebral Augmentation System will decrease the set time of StabiliT ER² Bone Cement.

Minimum bone cement Set Time Using StabiliT ER ² Bone Cement At 23°C	
With Warming	35 minutes*
Without Warming	51 minutes

* With 5:00 minute start time post-mix

- Wear safety glasses or a face shield when delivering the bone cement.
- Ensure that all luer lock connectors are tightened securely. Improperly secured connections could result in disconnection during injection.
- Exercise caution in cases involving extensive vertebral destruction and significant vertebral collapse (i.e., the vertebral body is less than 1/3 of its original height). Such cases may lead to a technically difficult procedure.

ADVERSE EVENTS

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements for vertebroplasty or kyphoplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism and cardiac embolism. Although the majority of these adverse events present early within the post-operative period, there have been some reports of diagnoses beyond a year or more after the procedure.

- Myocardial infarction
- Cardiac arrest
- Cerebrovascular accident
- Pulmonary embolism
- Anaphylaxis
- Diffusion of the bone cement outside the vertebral body: in the peripheral veins (pulmonary embolism), in the epidural plexus (myelopathy, radiculopathy), in the intervertebral disc

Other reported adverse events for acrylic bone cements intended for vertebroplasty or kyphoplasty include:

- Leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in embolism of the lung and/or heart or other clinical sequelae.

The most frequent adverse reactions reported with PMMA are:

- Transitory fall in blood pressure
- Thrombophlebitis
- Hemorrhage and hematoma
- Superficial or deep wound infection
- Bursitis
- Short-term cardiac irregularities
- Heterotopic bone formation

Other potential adverse events reported for PMMA include:

- Pyrexia
- Hematuria
- Dysuria
- Bladder fistula
- Transitory worsening of pain due to heat released during polymerization
- Nerve entrapment and dysphasia due to extrusion of the bone cement beyond its intended application
- Adhesions and stricture of the ileum due to heat released during polymerization

Potential adverse events associated with kyphoplasty or vertebroplasty include:

- Pneumonia
- Intercostal neuralgia
- Collapse of a vertebra adjacent to the one injected, due to an osteoporotic disease
- Pneumothorax
- Extravasation of bone cement into soft tissue
- Fracture of a pedicle
- Rib fracture in patients with diffuse osteopenia, especially during thoracic kyphoplasty procedures, due to the significant downward force exerted during Delivery Cannula insertion
- Compression of the spinal cord with paralysis or loss of feeling

PREPARATION AND USE










1. Turn on the Controller and ensure it passes self test prior to use.
2. Check packaging for damage prior to placing contents in sterile field.
3. Remove product from package using standard sterile technique.
4. Check all components for damage.
5. Follow the Controller Operating Manual for proper preparation.
6. StabiliT Introducer placement: Under fluoroscopic guidance place the StabiliT Introducer into the middle third of the vertebral body.
7. Once the StabiliT Introducer is positioned in the vertebral body remove the Stylet with a counterclockwise turn leaving the Working Cannula in place.
8. Create a cavity to stage bone cement delivery using the VertecoR StraightLine Cement Staging Osteotome and/or the VertecoR MidLine Cement Staging Osteotome. Follow the specific IFU of the Osteotome(s) to ensure proper use.
WARNING: Use imaging guidance and follow Osteotome IFU to avoid patient injury.
9. Bone cement mixing may commence at any time after room temperature is set on the Controller (per the Controller’s Operator Manual).
10. Mix bone cement per the ER² Saturate Mixing System IFU.
 - a) One minute prior to bone cement delivery(see Table 1) remove the Filter and Funnel Assembly. Then clean the Cement Syringe of excess bone cement and completely thread the Cement Syringe into the AE.
 - b) Thread the Master Syringe onto the Cement Syringe.
CAUTION: Ensure Master Syringe is FULLY threaded onto bone cement Syringe before proceeding. Not doing so can cause user injury or device malfunction.
11. Bone cement delivery on the Controller will be enabled once all connections are made per Controller’s Operator Manual.
12. Detach the small collection syringe at the end of the Hydraulic line. De-air the Hydraulic Syringe and line using the purge fixture attached to Hydraulic Syringe.
CAUTION: Failure to remove the small collection syringe prior to de-airing Hydraulic Sub Assembly may result in device damage.
CAUTION: Failure to fully de-air the Hydraulic Sub Assembly may result in device malfunction for cement delivery.
13. Connect the Hydraulic Sub Assembly to the Controller by pushing the Hydraulic Syringe into the receptacle on the Controller and rotating clockwise.
14. Connect the Hydraulic Line to the Master Syringe and press the ENTER Button  on the MultiPlex Controller or the PURGE Button  on the MultiPlex II Controller until bone cement exits the AE. Wipe excess bone cement from AE.
15. Start of bone cement delivery should be in accordance with table below. After the appropriate time (per table below), press ENTER Button  on MultiPlex Controller or the PURGE Button  on the MultiPlex II Controller until bone cement exits the AE.

TABLE 1: TIMING OF VARIOUS ACTIVITIES AT DIFFERENT AMBIENT TEMPERATURES

Activity	Ambient Temperature		
	18-19° C (65-67° F)	20° C (68° F)	21-23° C (69-74° F)
Bone Cement Saturation and Preparation (See Bone Cement IFU)	0-10 minutes	0-5 minutes	0-5 minutes
Bone Cement Delivery	10-52 minutes	5-47 minutes	5-42 minutes
Working Time	42 minutes	42 minutes	37 minutes

WARNING: Failure to follow the StabiliT Vertebral Augmentation System,StabiliT ER² Bone Cement and ER² Saturate Mixing System recommendations for operating parameters, delivery, working time or Cannula removal time may negatively affect the outcome of the procedure including inadvertent clogging of the AE or trapping of the Cannula.

WARNING: DO NOT deliver bone cement through the Working Cannula of StabiliT Introducer. Device damage and/or patient injury may occur.

























16. Start the RF activated bone cement delivery through the AE by pressing the BLUE Button on the Hand Switch once. A tone and the symbols  (RF) and  (bone cement delivery motor) on the Multiplex Controller or symbols  (RF) and  (bone cement delivery motor) on the MultiPlex II Controller display indicate the RF is activated and bone cement delivery motor is active. Press the BLUE Button again to stop delivery and wipe all excess bone cement from the AE luer.
17. Attach the LDC to the AE.
18. Press the BLUE Button on the Hand Switch to start RF activated bone cement through the LDC. Once bone cement exits the tip, press the BLUE Button on the Hand Switch to stop bone cement flow and wipe tip clean.
19. Under fluoroscopic guidance, while stabilizing the Working Cannula insert the LDC until the rotating wheel contacts the Working Cannula luer. Rotate the wheel to lock the LDC to the Working Cannula.
CAUTION: LDC must be used only with the Working Cannula properly positioned.
20. Under fluoroscopic guidance,deliver bone cement into vertebral body by pressing BLUE Button on Hand Switch.
CAUTION: For best bone cement results: once bone cement has been purged through the AE and LDC, MINIMIZE stops in delivery. When stopping delivery, minimize stop duration to less than 1 minute.
21. To stop bone cement delivery, press the BLUE Button again on the Hand Switch. The symbols for RF and bone cement delivery will extinguish on the Controller display.
CAUTION: Cement Syringe can be under high pressure. When BLUE Button is pressed to stop bone cement delivery, a small amount of bone cement may continue to flow. If additional bone cement delivery is not desired, then, disengage the LDC from the Working Cannulaand remove from the patient immediately following delivery and immediately insert the Introducer Stylet into the Working Cannula.
If the MultiPlex Controller displays “Possible Occlusion, Reposition Cannula,” the bone cement is encountering resistance and is building pressure towards pressure limit. Repositioning the LDC in the vertebral body may relieve bone cement pressure. LDC repositioning should always be performed under fluoroscopic guidance.
22. If “Check System”displays on the MultiPlex Controller or the Pressure Bars Flash on the MultiPlex II Controller during delivery,the system will automatically stop bone cement delivery and retract the hydraulic shaft to reduce pressure. If there is bone cement remaining to be delivered in the Cement Syringe:
 - a. While stabilizing the Working Cannula, remove the LDC and immediately insert the Introducer Stylet into the Working Cannula.
 - b. Press the BLUE Button on the Hand Switch and see if bone cement can be delivered from the end of the LDC.
 1. If so, stop delivery, clean bone cement from end of LDC, remove Introducer stylet,reinsert LDC into Working Cannula and reinitiate bone cement delivery.
 2. If not, wait 5 seconds to relieve pressure and detach LDC from AE.
 - a. Press the BLUE Button to try and deliver bone cement through AE.
 - b. If bone cement can be delivered through AE, replace the LDC.
 - c. If no bone cement exits AE, wait 5 seconds and replace AE and LDC.
 - c. After replacing AE and reattaching AE Cable, the MultiPlex Controller will confirm recognition by displaying the  AE icon and the MultiPlex II Controller will confirm recognition by removing the AE Icon.
 - d. Initiate bone cement delivery with RF by pressing the BLUE Button on the Hand Switch once. Stop delivery by pressing the BLUE Button a second time when bone cement exits the LDC. Wipe bone cement from end of LDC and re-insert into Working Cannula of the Introducer.
 - e. Under fluoroscopic guidance, continue bone cement delivery by pressing the BLUE Button on the Hand Switch once.

23. If additional bone cement is required an additional bone cement mix may be started in parallel to delivery of the first mix.
- a. To work in parallel, open another package of StabiliT ER2 Bone Cement, Hydraulic Sub Assembly, Master Syringe, LDC, and AE. When starting the second bone cement mix press the ORANGE Button on the Hand Switch to start a second timer.
 - b. If working in parallel is not desired, simply prepare all components as done for the first bone cement mix and delivery.
- NOTE:** In order to start delivery of a second bone cement mix press the REMIX/RESTART Button. This will retract the hydraulic drive shaft to its starting position to allow insertion of a new Hydraulic Syringe. Retraction may take as long as 80 seconds. When the hydraulic shaft has fully withdrawn, the Controller display will either display 0:00 or if the second timer was started, it will automatically display the time elapsed on the second timer.
- CAUTION:** Following completion of bone cement delivery, remove the LDC within 1 minute and immediately insert the Introducer Stylet into the Working Cannula.
- CAUTION:** Do not remove the Hydraulic Syringe until the hydraulic drive shaft has begun to withdraw.
- CAUTION:** If bone cement delivery needs to be stopped and the Hand Switch is not responsive, pressing the STOP or REMIX/RESTART Button on the Controller panel will stop delivery.
24. If no additional bone cement delivery is required remove Working Cannula along with the attached Introducer Stylet.
- WARNING:** Removal of the Working Cannula must be performed with Stylet inserted by rotation and axial motion. DO NOT bend Working Cannula sideways, patient injury may occur.

STORAGE & HANDLING

Handle with care. Store in original packaging in a clean, cool, and dry location. Avoid exposure to temperature and humidity extremes.

SYMBOL GLOSSARY

SYMBOL	DESIGNATION	SYMBOL	DESIGNATION
	Caution: Consult accompanying documents. Read instructions prior to use.		Use By: YYYY-MM-DD
	Sterilized using Irradiation		Keep away from sunlight
	Sterilized using Ethylene Oxide		Keep away from moisture
	Sterilized using Aseptic Processing Techniques		Flammable
	Lot Number		Single Use Device, DO NOT REUSE
	Catalog Number		Store below 25°C
	No Latex		Manufacturer
	Do not use if package is opened or damaged		Diamond tip
	Short		Bevel Tip
	Long		Cannula Gauge
	Device Length in Centimeters		Introducer Gauge/Locking Delivery Cannula Gauge
	Do not Resterilize		Quantity



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